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In re Application of Maertens et al

Serial No.: 10/685,435

Attorney Dkt No.:

Filed: 16 October 2003

2551-130

Decision on Petition

This is in response to the petition under 37 CFR 1.144 filed 02 May 2005, to request review of a restriction requirement.

## **BACKGROUND**

A review of the file history shows that this application was filed under 35 USC 111(a) on October 16, 2003 as a divisional of application 09/566,266, filed May 5, 2000, now US 6,855,318, which was a continuation of PCT/EP98/07105, filed November 6, 1998.

On 9 September 2004, the examiner mailed a restriction requirement dividing claims 23-31 into eight groups and a species election of a single polypeptide sequence from among SEQ ID NO:1-16 and 37 if any one of group I, III, V or VII is elected and election of polypeptides from among SEQ ID NO:17-36 if any one of groups II, IV, VI or VIII is elected.

In the response filed on 12 October 2004, applicants elected Group I, claims 23-25 and 29. Applicants elected SEQ ID NO: 15 with traverse and for purpose of initial search only, arguing that Examiner needs to search the complete breadth of the pending claims and withdraw the species election requirement, with a note that the parent application includes allowed claims which read on multiple sequences.

On 30 December 2004, the examiner mailed a first Office action on the merits acknowledging the election of the groups and the species, found the traversal nonpersuasive with respect to the species election among the various sequences, noting that under the test of In re Harnisch, 206 USPQ 300 (CCPA 1980), the claimed sequences fail as a proper Markush Group because they share no common substantial structural feature

and therefore the sequences represent independent inventions (for which no generic linking claim has been provided) because of which there is no requirement to extend the search to additional species (MPEP 809.02), and made the restriction requirement FINAL.

In response to the Office action of 12-30-2004, applicants filed the instant petition, accompanying arguments and amendments of the claims on 5-2-05. Applicants have petitioned to review the restriction requirement for a HCV E2 envelop peptide consisting of a single amino acid sequence.

## DISCUSSION

The application, file history and petition have been considered carefully.

The petition requests that in addition to examination of the elected invention directed to protein having SEQ ID No 15, examination of the proteins having SEQ ID Nos: 1-14, 16 and 37, in view of MPEP 803.04 be made. This is not persuasive. MPEP 803.04 is directed only to a waiver for restriction requirement with regard to nucleic acid inventions described by nucleotide sequences. The Office has not issued any waiver with respect to restriction requirement among protein inventions.

The petition argues that it would not be a serious burden to search and examine all the peptides together. The petition points to common classes and subclasses which were searched during examination of parent serial number 09/566,266. MPEP 808.02(c) points to a different field of search as grounds for establishing burden if restriction is to be required. It is noted that the literature and sequence database search is more pertinent than class and subclass searches for inventions claimed by polypeptide sequences. Furthermore, it is unlikely that applicants would accept prior art obtained by a search for one sequence in a rejection over a second sequence.

Applicant is reminded that restriction requirement is subject to the discretion of the examiner and thus what is done in one application is not necessarily relevant to another application. MPEP 811.04 states that a restriction requirement may be proper in a divisional application even though the inventions were grouped together in a parent application.

The request for withdrawal of the election of species is not persuasive because the peptides do not share a common structure which is essential to the common utility, per MPEP 803.02. A review of two randomly selected sequences, SEQ ID No 1, and 13 with elected SEQ ID No 15 shows no apparent sequence similarity.

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Ser lie Tyr Pro Gly His Ile Thr Gly His Arg Met Ala Trp Asp Met

1 5 10 10 15

Met Met Asn Trp Ser Pro Thr Thr Ala Leu Val Val Ser Gln Leu Leu

20 25 30

Arg Ile

4600- 1

Tyr Gln Val Arg Asn Ser Thr Gly Leu Tyr His Val Thr Asn Asp Cys

1 10 15

Pro Asn Ser Ser Ile Val Tyr Glu Ala Ala Asp Ala Ile Leu His Thr

20 25 36

Pro Gly Cys

35

4600- 13

His Val Asp Leu Leu Val Gly Ala Ala Ala Phe Cys Ser Ala Met Tyr

1 1 1 15

Val Gly Asp Leu Cys Gly Ser Val Phe Leu Val Ser Gln Leu

20 25 30
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The request for examination of independent or distinct inventions which are few in number or closely related, in view of MPEP 803.02, is not persuasive because the original claims recited in the alternative 17 amino acid sequences. This is not considered to be few in number. Furthermore, as set forth above, the sequences are not closely related in structure. Additionally, there is nothing on the record to suggest that the HCV envelop proteins are obvious variants of each another. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Finally, even if the sequences were encompassed by an allowable generic claim, written in the format such as "A HCV envelop 2 protein" the restriction to non-elected species would be maintained as long as there is one claim directed to one of the additional species embraced by an allowable generic claim which is not in the required form, i.e., does not require all the limitations of an allowable claim. See MPEP 809.02(c). Claim 24, for example, is anticipated by Maertens et al (WO 96/04385) or Dreesman (WO93/06488). Therefore the elected invention, as broadly claimed, is not free of the prior art. Any request to extend the search in view of election of species practice or linking claim practice is not persuasive absent (1) a novel and unobvious species that contains a common structure essential to a common utility with the non-elected species or (2) an allowable generic linking claim.

## **DECISION**

For these reasons, the petition to withdraw the restriction requirement is **DENIED**.

Any request for consideration must be filed within two (2) months of the mailing date of this decision.

Applicants remain under obligation to reply to the Final Office action mailed 31 July 2005 with in the response time specified therein or as extendable under 37 CFR 1.136(a).

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 571-273-8300.

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